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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/882,376	06/18/2001	John Peter Morseman	31676.0248	6731

21967 7590 03/03/2006

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EXAMINER

COUNTS, GARY W

ART UNIT PAPER NUMBER

1641

DATE MAILED: 03/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/882,376

Applicant(s)

MORSEMAN ET AL.

Examiner

Gary W. Counts

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10/19/05 & 09/29/05.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 1 and 2 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### **Status of the claims**

The Supplemental amendment filed October 19, 2005 and the Declaration Filed September 29, 2005 is acknowledged and has been entered.

### **Rejections Withdrawn**

Applicant's amendment to claim 3 to remove the recitation "manner" has overcome the indefiniteness of claim 3 and therefore the 112 2<sup>nd</sup> rejection has been withdrawn.

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 3-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al (homogenous Proximity Tyrosine Kinase Assays, Analytical biochemistry 269, 94-104 (1999)) in view of Applicant's statement regarding the sale of product (cross-linked allophycocyanin which had not been exposed to strongly chaotropic agents) (see IDS filed December 3, 2003).

Park et al disclose a method for quantitating an analyte by measuring time resolved transfer of fluorescence energy to or from a label quantitatively associated with analyte. Park et al disclose measuring the energy transferred from donor compounds to absorb light energy and then transfer this energy to cross-linked allophycocyanin. Park et al disclose the energy donor can be europium (abstract).

Park et al fail to specifically teach that the cross-linked allophycocyanin has not been exposed to strongly chaotropic agents after cross-linking, which is available for sale by Applicant more than one year prior to the filing date of this application.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to select the cross-linking agent as described in the statement provided by Applicant (see above) as an alternative for the cross-linking agent of Parks et al. And it appears both cross-linking agents would perform equally

well in Time-Resolved Fluorescence Assays, therefore a skilled artisan would have a reasonable expectation of success in selecting either cross-linking agent for performing the assay.

5. Claims 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al and Applicant's statement regarding the sale of product (cross-linked allophycocyanin which had not been exposed to strongly chaotropic agents) (see IDS filed December 3, 2003) in view of Applicant's admission of prior art.

Park et al and Applicant's statement differ from the instant invention in failing to specifically teach at least two distinct donor species present in different formats.

On page 9, lines 25 – page 10, line 8 in the specification Applicant discloses that the dye of this invention can be used with any known format for FRET. Applicant discloses the known formats. It would have been obvious to one of ordinary skill in the art to incorporate the cross-linked allophycocyanin of Applicant into different well known formats of FRET as disclosed by Applicant for quantitating an analyte by measuring time resolved fluorescence of a label quantitatively associated with the analyte.

### ***Response to Arguments***

6. Applicant's arguments filed October 19, 2005 and September 29, 2005 and the Declaration filed September 29, 2005 have been fully considered but they are not persuasive.

Applicant argues that the Declaration by Mark Wesley Moss demonstrates that a skilled artisan would clearly not have a reasonable expectation of success in substituting Applicants' product for the conventional cross-linked APC used in

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accordance with the Park publication. Applicant states that one skilled in the art would have no expectation of success in choosing Applicants' product to achieve any particular technical benefit in fluorescence assays. Consequently, one of skill in the art would have no motivation to substitute Applicants' product for convention cross-linked APC in fluorescence assays. This is not found persuasive because as stated above and in the previous office action Applicants' product would be an obvious substitution for the conventional cross-linked APC in fluorescence assays and further the fact that Applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. Further, with respect to the motivation since the only known art use for cross-linked allophycocyanin was for assays and given the admission that cross-linked allophycocyanin which had not been exposed to strong chaotropic agents was on sale December 22, 1998 (See IDS filed December 3, 2003, Applicants's statement regarding the sale of product) prior to the priority date (06/16/200) of the instant application (09/882,376), and given that there was no known or accepted use for cross-linked allophycocyanin other than for accepted assays it would have been obvious to select the cross-linking agent, described in the statement provided by Applicant (See IDS filed December 3, 2003, Applicant's statement regarding the sale of product) as an alternative for the cross-linking agent of Parks et al.

Since the only known or accepted use of cross-linked allophycocyanin was in assay methods, the cross-linked allophycocyanin purchased from Applicant would have

been used in the assay methods known in the art and therefore the methods would obviously yield improved analytical results and improved sensitivity.

Applicant states that the Declaration filed 09/29/05 establishes how Applicants product generates improved results over conventional cross-linked APC in time resolved fluorescence tyrosine kinase assays. This is not found persuasive because a review of the declaration particularly paragraph 15 and paragraph 19 shows that the conventional cross-linked APC and Applicants' product produced similar results when used in assay methods, which would further confirm that Applicants' product would be an obvious alternative for the conventional cross-linked APC.

Applicant also states that the declaration establishes that Applicants' product was indeed not offered to be sold more than one year prior to the filing date of the present application for the purpose of using Applicants' product in assays involving time-resolved fluorescence (see paragraph 4 of the Declaration). This is not found persuasive because paragraph 4 states that "To the best of my knowledge, the third party to whom Applicants offered to sell Applicants' product did not use Applicants product more than one year prior to the filing date of the '376 application for a use that involved time-resolved fluorescence. This is not found persuasive because Applicant has not provided any evidence that it was not sold for this purpose.

Applicant further directs Examiners attention to Examples 6 and 8 of the specification which show improved signal-to-noise ratios. This is not found persuasive because Applicant has not provided evidence that the signal-to-noise ratio increase was unexpected nor has Applicant disclosed any statistical significance of the increases.

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Also, as stated in the previous office action it appears Example 8 is directed to manufacturing advantages of SL-APC (not exposed to strong chaotropic agent) and not for increased sensitivity in assays. Example 8, page 18 discloses that SL-APC is an alternative acceptor which retains all the characteristics of native APC while obtaining the same stability results as XL-APC at a reduced price and that SL-APC could provide a low cost alternative to XL-APC in this system if it provides results that did not sacrifice sensitivity. Further, page 19, lines 17-23 discloses that the dyes had signal intensity of the same magnitude, with SL-APC edging out XL-APC in signal intensity and that SL-APC provided competitive sensitivity to XL-APC without the need for extensive chemical cross-linking and purification (manufacturing advantage). Further, since it would have been obvious to one of ordinary skill to substitute the cross-linked allophycocyanin as described in the statement provided by Applicant (see above) as an alternative for the cross-linked allophycocyanin of Parks et al, one of ordinary skill in the art would expect the combination of Parks et al and applicants allophycocyanin would possess the benefits which applicant is arguing.

### ***Conclusion***

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the



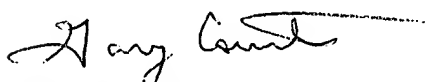
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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

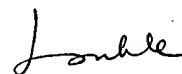
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Gary Counts  
Examiner  
Art Unit 1641  
February 24, 2006



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02/24/06